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# REMARKS

# Interview Summary

Applicants wish to thank the Examiner for the telephonic interview on 30 June 2006. During the interview, the Applicants further explained the invention and the performance of the invention. Applicants and the Examiner did not discuss any specific claim amendments.

# Claim Status

Claims 1-35 are pending in the present application. No additional claims fee is believed to be due.

Claims 1, 2, 18, 19, 28, 32, and 34 have been amended to more specifically indicate the time that the composition is retained in the teeth. Support for these amendments is found in the specification on pages 6-7. Claims 6-8, 22, and 23 have been amended. Support is found in the specification on page 8.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

# Rejection Under 35 USC §112, Second Paragraph

The Office Action states that Claims 1-2, 4-5, 13, 19-21, and 29-30 are rejected under 35 U.S.C. §112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Specifically, the Examiner objects to the use of "from about," "less than about," and "for at least about."

It is respectfully submitted that the noted terms as used in the present claims do not render the claims indefinite. As stated in the MPEP under 2173.05(b) A, the term "about" has been held to be "clear, but flexible" citing Ex parte Eastwood, 163 USPQ 316 (Bd. App. 1968) and W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540,

220 USPQ 303 (Fed: Cir. 1983). In Eastwood, the Board of Appeals held that the term "about" used to define an area is definite, stating as follows:

The descriptive word "about" is not indefinite as argued by the examiner. Its meaning is not as broad and arbitrary as contended by the examiner. Rather, the term is clear but flexible and is deemed to be similar in meaning to terms such as "approximately" or "nearly".

Even in Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200; 18 USPQ.2D 1016 (Fed. Cir. 1991), which held that claims reciting "at least about 160,000" in defining specific activity of an erythropoietin protein were indefinite, the Court cautioned that such decision was reached because of the particular facts of the case, wherein the term could possibly include a value disclosed in the art. As stated therein:

In arriving at this conclusion, we caution that our holding that the term "about" renders indefinite claims 4 and 6 should not be understood as ruling out any and all uses of this term in patent claims. It may be acceptable in appropriate fact situations, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1557, 220 U.S.P.Q. (BNA) 303, 316 (Fed. Cir. 1983) ("use of 'stretching . . . at a rate exceeding about 10% per second' in the claims is not indefinite"), even though it is not here.

It is respectfully submitted that the terms "from about," "less than about," and "for at least about" are recognized in US law to provide some expansion of the literal scope of the claims beyond the numeric range stated and that the present Claims are fully definite as required by 35 U.S.C. §112, Second Paragraph. Therefore, the rejection of Claims 1-2, 4-5, 13, 19-21, and 29-30 should be withdrawn.

#### **Double Patenting Rejection**

In the Office Action dated November 7, 2005, Claims 1-35 were provisionally rejected under the doctrine of double patenting over claims 1-17 of Application No. 10/706,103. Though the Office Action dated May 5, 2005 withdraws the double patenting rejection, to insure a complete record, applicants are submitting a terminal disclaimer to overcome the rejection.

# Rejection Under 35 USC §102 Over Lawlor

The Examiner has rejected Claims 1-2, 4, 6-10, 12-16, 30, 32, and 34 under 35 U.S.C. §102(a) and (e) as being anticipated by Lawlor. Applicants respectfully traverse.

The Examiner states that the retentive agents of the present invention are disclosed in Lawlor and that the retentive agents will have the same result in the present invention as they do in Lawlor. Specifically, the Examiner reasons that any composition sucked or chewed in the mouth leaves some residue on the surface of the tooth, thereby achieving the same effect as the present invention.

The Examiner further states that if the prior art structure is capable of performing the intended use, then it meets the claim. But the claimed invention, as specified in amended Claims 1, 2, 18, 19, 28, 32, and 34, is intended to remain in the subject's tooth for at least 5 minutes, where it can, among other things, provide extended delivery of oral care active agents directly to the tooth surfaces or in the oral cavity. Because Lawlor does not teach or suggest that its composition remains in the oral cavity for that length of time, it is not capable of performing the claimed invention's intended use.

Lawlor discloses that its composition is retained in the oral cavity for only 5 to 30 seconds. (col. 24, lines 32-34). In fact, Lawlor teaches away from the composition remaining very long in the oral cavity, stating that it is preferred that its composition "has disappeared by 5 minutes, preferably by 4 minutes so that the material does not abrade the dentin or so that the product does not have a gritty residue." (col. 17, lines 27-30).

In contrast, the present invention fully intends for a visible residue to remain in the tooth for at least 5 minutes. The claimed invention is capable of being visible on the tooth 5 minutes after the subject chews two tablets of the composition for about 5 to 30 seconds, brushes his or her teeth for about 30 seconds, expectorates the slurry created from the brushing, and then rinses with about 10 mils of water and expectorates again.

For a claim to be anticipated, each and every element of the claim must be present in the prior art reference. Given that Lawlor does not teach or suggest that its composition will remain in the oral cavity for the same length of time as the present invention, it is respectfully submitted that Lawlor does not anticipate the present invention.

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In Claims 6-8, 22, and 23, applicants have provided alternate lists of retentive agents in which none of the listed retentive agents are disclosed in Lawlor.

For these reasons, applicants respectfully submit that the rejections should be withdrawn.

# Rejection Under 35 USC §103(a) Over Lawlor in view of Aberg

Claims 1-34 have been rejected under 35 USC §103(a) as being unpatentable over Lawlor in view of Aberg. Applicants respectfully traverse.

The Examiner states that one of ordinary skill in the art would have combined the teachings of Lawlor with those of Aberg to make an oral dentifrice tablet that leaves a substantial amount of the composition on the tooth surface. Applicants reiterate that the present invention creates an intact hydrated mass that remains visible on the tooth for 5 minutes to about 60 minutes. As previously discussed, Lawlor teaches away from its composition remaining in the oral cavity as long as the claimed invention. Lawlor states that its composition should remain in the oral cavity for only 5 to 30 seconds, and that it should have "disappeared" by 5 minutes. (col. 24, lines 32-34 and col. 17, lines 27-30).

Similarly, the composition in Aberg does not remain in the oral cavity for the same extended time as the present invention. In Aberg, the composition is chewed and then swished around the mouth for about 1 to 2 minutes (preferably at least 2 minutes) and then swallowed. (page 5, lines 11-13). Aberg, like Lawlor, teaches nothing about a visible amount of the composition remaining on the tooth after swallowing. Furthermore, Aberg teaches away from the claimed invention when it specifies that it achieves its results through the mechanical action of chewing and swishing for 1 to 2 minutes. (page 5, lines 11-15). In contrast, the present invention remains in the subject's tooth for at least 5 minutes, where it can, among other things, provide extended delivery of oral care active agents directly to the tooth surfaces or in the oral cavity.

Neither Lawlor nor Aberg teach or suggest that their respective compositions will remain visible on the tooth for 5 minutes to about 60 minutes. Lawlor and Aberg both specifically teach away from that result. Therefore, one having ordinary skill in the art would not have been motivated by the teachings of Lawlor and Aberg to develop the present invention.

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# Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-35 is respectfully requested.

Respectfully submitted,

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